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May 16, 2011

VIA ECF AND FACSIMILE

The Honorable Madeline C. Arleo, U.S.M.J.
United States District Court
Martin Luther King, Jr. Federal Building
50 Walnut Street, Room 2060
Newark, New Jersey 07101

Re: *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*
Civil Action No. 10-6108 (SDW) (MCA)

Dear Judge Arleo:

This firm, together with Jones Day and Richard G. Greco PC, represents plaintiff Jazz Pharmaceuticals, Inc. ("Jazz Pharmaceuticals") in the above-referenced matter. We write regarding (1) the pretrial schedule in this case; and (2) Jazz Pharmaceuticals' difficulties in preparing its infringement contentions because of Roxane Laboratories Inc.'s ("Roxane") and its supplier Norac Inc.'s ("Norac") failure to produce samples or consent to disclosure of their confidential material to a retained expert.

I. Scheduling Order Dispute

The parties have reached agreement regarding almost all of the proposed scheduling dates. (See proposed dates 1, 3-14 and 16 of Plaintiff's Proposed Schedule, attached hereto as Exhibit A.) Despite lengthy negotiations, however, the parties have reached an impasse concerning the exchange of expert reports and proposed dates for the final pretrial conference and trial.

A. Expert Report Dates

Jazz Pharmaceuticals has proposed that the parties submit the usual opening, response and reply expert reports. (See Ex. A., proposed dates 13-15.) In the opening reports, the parties would disclose their experts' opinions on the issues for which they bear the burden of proof. For example, Jazz Pharmaceuticals would offer opening expert reports on infringement while Roxane would offer expert reports concerning invalidity. The parties would then exchange opposition expert reports that would respond to the opening reports, followed by reply expert reports (if any) in response to the opposition reports. This straightforward and common

approach would allow each party's experts to disclose the full scope of their opinions, including responses to issues raised in the opposing party's expert reports.

Roxane, apparently, would rather preclude reply reports, leaving any response to the opposition report undisclosed. Furthermore, Roxane seeks to detach opening reports from the burden of proof by proposing that Jazz Pharmaceuticals' opening expert reports should provide evidence of secondary considerations in rebuttal to Roxane's obviousness argument before Roxane even offers its experts' opinions concerning obviousness. (See April 27, 2011 email from M. Goodin to G. Brier, attached hereto as Exhibit B.) In Jazz Pharmaceuticals' view, this is not a sensible approach. Secondary considerations are a response to an argument of invalidity on which the defendant bears the burden of proof. Roxane's proposal would force Jazz Pharmaceuticals to guess as to the contour of Roxane's invalidity case when it files its opening reports. Jazz Pharmaceuticals' task would be further complicated by the number of patents-in-suit and the overly broad scope of Roxane's recently served invalidity contentions. (See, *e.g.*, Roxane's contentions regarding the '219 patent alleging that the patent claims "are invalid over one or more of the following [nine] references, alone (for anticipation and/or obviousness) or in combination (for obviousness)," attached hereto as Exhibit C.) Jazz Pharmaceuticals submits that it is entitled to see Roxane's actual invalidity case in its expert reports before offering a rebuttal. Thus, Jazz Pharmaceuticals should not be required to submit an expert opinion in support of secondary considerations of nonobviousness until its opposition expert reports are due.

Furthermore, the parties have already agreed to close expert discovery on August 22, 2011, eight months before expiration of the 30-month stay. Accordingly, the inclusion of reply expert reports cannot delay the trial date or endanger the parties' ability to obtain a decision on the merits prior to expiration of the 30-month stay. Accordingly, Jazz Pharmaceuticals' proposal for the exchange of expert reports should be adopted over Roxane's.

B. Pretrial Conference and Trial Dates

Jazz Pharmaceuticals has proposed that these dates should be designated "to be set by Court." This proposal is based upon Jazz Pharmaceuticals' understanding that Your Honor will not be setting the dates for the final pretrial conference and trial until later in the case in coordination with Judge Wigenton. Roxane apparently does not disagree, stating that "we do not see the harm in including those dates in the proposed schedule, even if Judge Arleo indeed ultimately defers scheduling those dates at this time." (Ex. B.) Roxane has insisted, nevertheless, on proposing set dates for the final pretrial conference and trial. (*Id.*) Jazz Pharmaceuticals submits that there is no reason to propose specific dates for events that the parties agree will not be set by the Court at this time.

For the above reasons, Jazz Pharmaceuticals respectfully requests that the Court enter Jazz Pharmaceuticals' proposed pretrial schedule, attached hereto as Exhibit A.

II. Jazz Pharmaceuticals' Infringement Contentions

At the February 7 initial scheduling conference, the parties discussed the need for Jazz Pharmaceuticals to obtain samples of Roxane's and Norac's sodium oxybate in order to complete its infringement contentions. At the March 22 follow-up conference, the Court set a June 1 due date for Jazz Pharmaceuticals' infringement contentions. In doing so, the Court commented that "[y]ou get the sample by next week, there should be no problem with having it well in advance of the June 1 date." (March 22 Tr. at 13, attached hereto as Exhibit D.)

Today — more than three months after the initial conference and almost two months since the follow-up conference — neither Roxane nor Norac has produced a single sample. Further, they have objected to allowing Jazz Pharmaceuticals' expert to review any of Roxane's or Norac's confidential information until a discovery confidentiality order is entered in this case. The dispute concerning the discovery confidentiality order relates only to in-house counsel's ability to review confidential information. The dispute has nothing to do with what information or materials may be viewed by a technical expert or a testing lab. Thus, there is no reason why the dispute regarding the protective order should delay the delivery of samples for testing or prevent Jazz Pharmaceuticals from consulting with its expert — all while the clock on its contentions has been ticking. Jazz Pharmaceuticals submits that this is unreasonable.

Moreover, there remains critical unresolved objections to Jazz Pharmaceuticals' subpoena to Norac — the party that manufactures the sodium oxybate concentrate for Roxane. A central issue on infringement regarding the formulation patents is how the pH of the sodium oxybate is adjusted. On February 9, 2011, Jazz Pharmaceuticals issued a subpoena to Norac from the Central District of California (where Norac is located) seeking, among other materials, documents concerning the addition of an acid and/or base, including GBL or sodium hydroxide, to sodium oxybate to adjust pH. Norac — represented by the same counsel as Roxane — contends that it has produced documents but has attempted to limit the scope of that production. A meet and confer on this issue is currently scheduled for May 18, as Norac's counsel is on trial before then.

Without testing or expert consultation, Jazz Pharmaceuticals will not be able to provide anything beyond cursory contentions on June 1. All of the technical questions Jazz Pharmaceuticals needs to answer to formulate its infringement contentions cannot be answered merely by attorneys reviewing the documents currently produced by Roxane and Norac. Instead, Jazz Pharmaceuticals needs to consult with its expert and testing laboratory to fully understand these highly technical documents and the nature of Roxane's accused product.

Accordingly, Jazz Pharmaceuticals submits that the timing of its infringement contentions should be modified. Specifically, Jazz Pharmaceuticals respectfully requests that the Court order Roxane and Norac to produce samples within seven days following the May 20 hearing scheduled before Your Honor relating to the discovery confidentiality order. Jazz Pharmaceuticals would then serve its contentions 30 days after it has received Roxane's and Norac's samples. This time would also allow counsel to consult with Jazz Pharmaceuticals'

retained expert. Further, this proposed extension would not upset any of the other scheduling dates that have been agreed upon by the parties. (*See* Ex. A., proposed dates 1, 3-14 and 16.) Thus, there will be no prejudice to Roxane or undue delay as a result of allowing a brief extension so that Jazz Pharmaceuticals may prepare meaningful contentions.

We would appreciate an opportunity to discuss the above issues with Your Honor at the hearing scheduled for May 20, 2011 at 2:00 p.m.

Respectfully yours,

Charles M. Lizza

Exhibits

cc: All Counsel (via e-mail)

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS, INC., **Plaintiff,** **v.** **ROXANE LABORATORIES, INC.,** **Defendant.**	**Civil Action No. 10-6108 (SDW)(MCA)** **Hon. Susan D Wigenton, U.S.D.J.** **Hon. Madeline C. Arleo, U.S.M.J.** **[PROPOSED] PRETRIAL SCHEDULING ORDER**

THIS MATTER having come before the Court for a status conference on May 20, 2011; and for good cause shown:

IT IS on this ___ day of May, 2011,

ORDERED THAT: The parties shall complete the following actions on the dates stated herein.

DISCOVERY AND MOTION PRACTICE

ACTION	DATES
1. Defendant serves non-infringement and invalidity contentions	April 14, 2011
2. Plaintiff serves infringement contentions and identifies asserted claims	30 days from the receipt of samples from Roxane and Norac[1]
3. Parties exchange proposed terms for construction and thereafter meet and confer to narrow issues	July 8, 2011

[1] This date was previously set by the Court as June 1, 2011.

4.	Parties exchange preliminary proposed constructions and identifications of intrinsic and extrinsic evidence and thereafter meet and confer to narrow issues	August 1, 2011
5.	Parties file Joint Claim Construction and Pre-hearing Statement	August 26, 2011
6.	Parties complete fact discovery related to claim construction	September 23, 2011
7.	Parties file opening Markman papers, including any expert declarations	October 19, 2011
8.	Deadline for motions to amend pleadings or add parties	December 5, 2011
9.	Parties complete expert discovery regarding Markman issues	November 18, 2011
10.	Parties file responsive Markman papers, including any responding expert declarations	December 19, 2011
11.	Parties propose schedule to the Court for Claim Construction Hearing	December 30, 2011
12.	Close of fact discovery	February 22, 2012
13.	Opening expert reports on issues for which the party bears the burden of proof	April 20, 2012[2]

[2] The due dates for expert discovery presume that the parties will have received a Markman ruling by those dates.

14.	Opposition expert reports	May 25, 2012
15.	Rebuttal expert reports	June 27, 2012
16.	Close of expert discovery	August 22, 2012
17.	Final pretrial conference	To be set by Court
18.	Trial	To be set by Court

MADELINE COX ARLEO
United States Magistrate Judge

Original: Clerk of the Court
cc: All Parties
Deputy Clerk
File

EXHIBIT B

Subject:
RE: Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.

From:
Goodin, Miki
04/27/2011 10:29 AM

To:
Gabriel Brier

Cc:
"Clement, Alan B.", 'Andrew S Chalson', "Wayda, Andrea L.", "Lizza, Charles M.", 'Daniel L Malone', "'F. Dominic Cerrito'", 'Mark Olinsky', "Noh, Peter H.", "rgreco@RGGLiberty.com", "Feder, Scott", "Hensler, Sarah A.", 'Theodora McCormick', "wbaton@saul.com", Eric Stops
Show Details

History: This message has been replied to.

2 Attachments

2008-11-20 Amendment to Pretrial Scheduling Order.pdf LLBL revised NYI_4363991_2_Revised Schedule 2.DOC

Dear Gabe,

Based on the statements in Roxane's initial invalidity contentions, it should come as no surprise to Plaintiff that Roxane will indeed allege invalidity based on obviousness in its opening expert reports. Accordingly, and assuming Plaintiff intends to serve expert reports on secondary considerations of nonobviousness, we propose that Plaintiff issue any such reports during the opening round because it bears the burden of proof on secondary considerations. *Demaco Corp. v. F. Von Langsdorff Licensing, Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988) ("In meeting its burden of proof [as to secondary considerations of nonobviousness], the patentee, *in the first instance* bears the burden of coming forward with evidence sufficient to constitute a prima facie case of the requisite nexus.") (emphasis added). Roxane would then respond to Plaintiff's experts' reports on the issue of secondary considerations of nonobviousness during the second round. *See id.* at 1393 .

Following this schedule would obviate the need for three rounds of expert reports and would help to prevent any unnecessary delays in the resolution of this case before the expiration of the 30-month stay of FDA approval. I have attached an order from another case in the District of New Jersey where the Court's scheduling order contemplates Plaintiff issuing any expert reports on secondary considerations during the first round wherein affirmative expert reports were exchanged. *See* Doc. 266, Nov. 20, 2008 Amendment to Pretrial Scheduling Order in *Eli Lilly and Company v. Actavis Elizabeth LLC, et al.*, Civil Action No. 07-3770 (DMC) (MF) (attached).

Regarding the final pretrial conference and trial date, we do not see the harm in including those dates in the proposed schedule, even if Judge Arleo indeed ultimately defers scheduling those dates at this time. If Plaintiff is strongly adverse to including a proposed date, we would be glad to indicate (as indicated in the attached revised proposed scheduling order) that the specific dates for the pretrial conference and trial are being proposed by Roxane, to give the Court sufficient time to render a ruling after trial (and for the parties to take any issues up on appeal) before expiration of the 30-month stay. Please let us know whether Plaintiff agrees to such a revision in the proposed pretrial scheduling order.

Sincerely,
Miki

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From: Gabriel Brier [mailto:gbrier@JonesDay.com]
Sent: Monday, April 25, 2011 12:21 PM
To: Goodin, Miki
Cc: Clement, Alan B.; 'Andrew S Chalson'; Wayda, Andrea L.; Lizza, Charles M.; 'Daniel L Malone'; 'F. Dominic Cerrito'; 'Mark Olinsky'; Noh, Peter H.; rgreco@RGGLiberty.com; Feder, Scott; Hensler, Sarah A.; 'Theodora McCormick'; wbaton@saul.com; Eric Stops
Subject: RE: Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.

Miki,

We do not agree with your proposal regarding expert reports. Roxane bears the burden of proof on invalidity. Therefore, under Plaintiff's proposal, Roxane would address that burden it its opening expert reports. To the extent Roxane alleges invalidity based on obviousness, Plaintiff would respond in its opposition expert reports, including providing any evidence of secondary considerations. Roxane could then respond to Plaintiff's secondary considerations evidence in Roxane's rebuttal expert reports. The parties would likewise exchange opening, opposition and rebuttal reports on other issues for which they bear the burden of proof. Please let us know whether Roxane agrees to such a three-round exchange of expert reports.

With respect to the final pretrial conference and trial date, Roxane appears to agree that Judge Arleo will not be setting these dates in her pretrial scheduling order. Yet Roxane continues to insist that the proposed schedule include these dates. We do not understand what the purpose would be of including dates in the proposed schedule that the parties agree will not be entered by the Court. Please let us know whether Roxane agrees to submitting the proposed schedule with "to be set by Court" in the spaces concerning the final pretrial conference and trial date.

Best regards,

Gabe

EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS, INC.,	)	
	)	
	)	
Plaintiff,	)	CIVIL ACTION NO.:
	)	2:10-cv-06108 (SDW) (MCA)
vs.	)	
	)	
ROXANE LABORATORIES, INC.,	)	
	)	
Defendant,	)	
	)	

ROXANE LABORATORIES, INC.'S INITIAL INVALIDITY AND NONINFRINGEMENT CONTENTIONS PURSUANT TO LOCAL PATENT RULE 3.6

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Attorneys for Defendant
Roxane Laboratories, Inc.

ROXANE'S NONINFRINGEMENT CONTENTIONS BEGINNING AT TAB 9 ARE HIGHLY CONFIDENTIAL AND ARE BEING PRODUCED AS OUTSIDE COUNSELS' ATTORNEYS' EYES ONLY UNTIL THE ENTRY OF A DISCOVERY CONFIDENTIALITY ORDER, PURSUANT TO L. PAT. R. 2.2

C. The claims of United States Patent No. 7,262,219 are invalid:

1. Roxane contends that claims 1-4 of United States Patent No. 7,262,219 ("the '219 patent") are invalid under 35 U.S.C § 112, ¶¶ 1 and 2 as lacking written description and being indefinite because the claims contradict themselves. Specifically, independent claims 1 and 4 require gamma-hydroxybutyrate and a pH adjusting agent, both of which function as preservatives in the claimed composition.

2. Roxane contends that claims 1-4 of the '219 patent are invalid under 35 U.S.C § 112 for at least the reasons set forth above. Additionally, and without prejudice or admitting that the claims are definite and/or capable of construction, Roxane further contends that the claims of the '219 patent are invalid over one or more of the following references, alone (for anticipation and/or obviousness) or in combination (for obviousness): United States Patent No. 5,840,331 ("the '331 patent") (ROXGHB002548-ROXGHB002569); United States Patent No. 4,983,632 ("the '632 patent") (ROXGHB002570-ROXGHB002575); and United States Patent No. 3,051,619 ("the '619 patent") (ROXGHB002576-ROXGHB002578); Chem Abstract ES302338 (Accession Number 1966:481550, CAN 65:81550, CAPLUS) ("CA 338") (ROXGHB002579); R.H. Roth, et al. "γ-butyrolactone and γ-hydroxybutyric acid-II. The Pharmacologically active form," *Int. J. Neuropharmacol.*, 5, 421-428 (1966) ("Roth") (ROXGHB002580-ROXGHB002590); M.D. Vickers, "Gammahydroxybutyric acid," *International Anesthesiology Clinics*: Spring 1969 - Volume 7 - Issue 1 – pp. 75-90 ("Vickers") (ROXGHB002591-ROXGHB002609); Morrison and Boyd, ORGANIC CHEMISTRY, 3RD EDITION, 1973 ("Morrison") (ROXGHB002610-ROXGHB002618); USP 23/NF18, 1995 ("1995 USP") (ROXGHB002619-ROXGHB002621); 21 CFR 184 (1998); and the HANDBOOK OF PHARMACEUTICAL EXCIPIENTS, (2nd. Ed., 1994) ("1994 HPE")(ROXGHB002622-ROXGHB002626).

EXHIBIT D

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS, INC., Plaintiff,	.	
vs.	.	Case No. 10-cv-06108
ROXANE LABORATORIES, INC., Defendant.	.	Newark, New Jersey March 22, 2011

TRANSCRIPT OF TELECONFERENCE
BEFORE THE HONORABLE MADELINE COX ARLEO
UNITED STATES MAGISTRATE JUDGE

APPEARANCES:

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contentions.

I think there is some merit to the defense argument that you don't need to fully have an analysis of the samples in order to do your infringement contentions when you have all the underlying documents that are contained in the ANDA and elsewhere. Certainly, you have the right to amend them. And you may not even need to amend them because if we can get the sample handled properly -- I had a representation that they'll let you know by today, the end of the day, if there's any problem with the lab. You get the sample by next week, there should be no problem with having it well in advance of the June 1 date.

But I don't want -- I'm aware of the -- I'm certainly guided by the 30-month stay, and I don't want to -- want to create a schedule that's -- puts a lot of pressure on the District Court at the end of the day to have this case resolved in light of the 30-month stay.

I should also say that there's absolutely -- the Jazz Pharmaceutical proposed schedule not only is it not consistent with the -- with the local patent rules, it doesn't seem to be any -- any logic for tieing defendant's obligations to receipt of samples by plaintiff. And that is just a -- a 90-day delay that is completely unnecessary.

If Mr. Lizza says to me -- Mr. Cerrito, look, I'm very close on June 1, I need another two weeks because I have